REMARKS

This responds to the Office Action dated on October 22, 2007. Claims 1, 5, 6, and 12 have been amended. Claims 7-11, and 13-20 have been cancelled. Claims 21-56 have been added. As a result, claims 1-6, 12, and 21-56 are now pending in this patent application.

Telephonic Interview Summary

Applicant thanks Examiner George Evanisko for extending the courtesy of a telephonic interview with Applicant's representatives, Suneel Arora and Edward Sandor, on October 30, 2007. The Examiner indicated that, with the present Request for Continued Examination (RCE), Applicant would be allowed to present new claims that are shifted from the previously pending claims, but that the Examiner would consider issuing a Restriction Requirement, as the Examiner deems appropriate, with respect to such new claims.

Request for Telephonic Interview

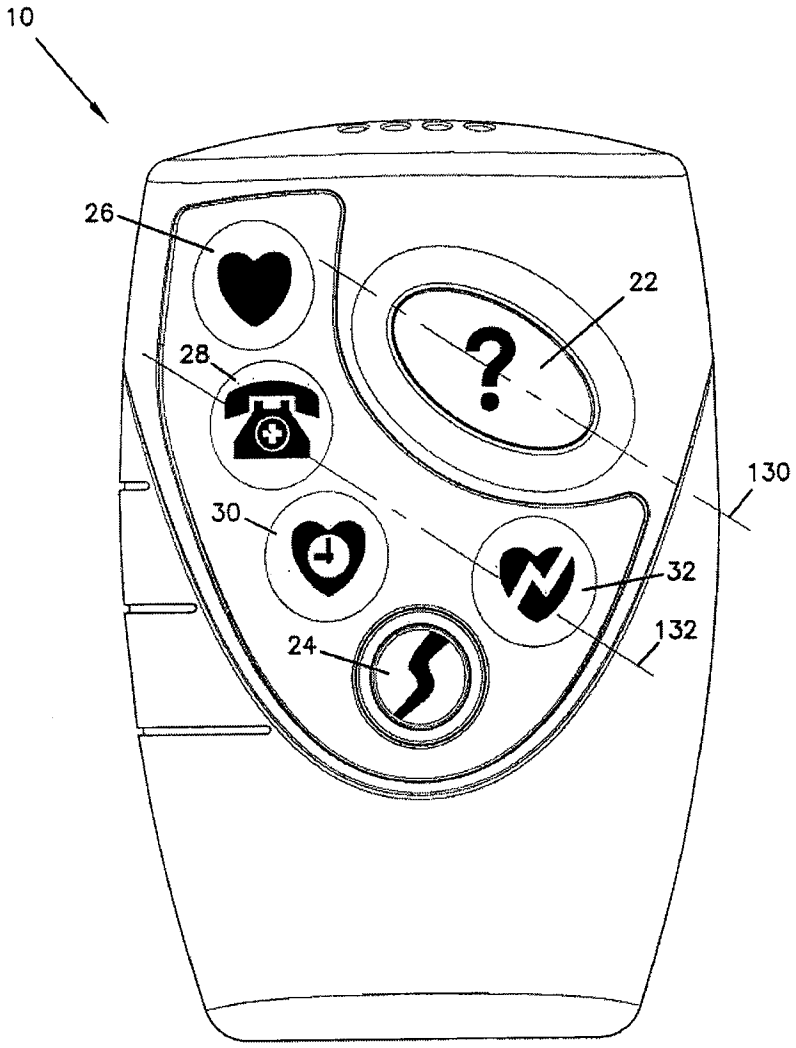
Applicant's representatives, Suneel Arora and Edward Sandor, respectfully request a further telephonic interview with the Examiner upon receipt of this response, in order to discuss the possibility of a Restriction Requirement, the merits of the present response, and to carry out telephonic prosecution of this patent application to mutually facilitate the examination. Applicant's representative, Suneel Arora, can be reached by telephone at 612-373-6951.

§112 Rejection of the Claims

Claims 1-20 were rejected under 35 U.S.C. § 112, first paragraph, as lacking adequate description or enablement. Applicant has amended claim 1 to overcome this rejection. Claim 1 recites the use of different "icons" with the "icons" differentiated from each other by the use of "different pictorial graphic shapes that convey information pictographically" (and therefore nontextually). Applicant respectfully submits that this constitutes a positive recitation, rather than a negative recitation, and is fully supported throughout the specification of the present patent application. An example is clearly shown in FIG. 22 of the present patent application, by

the icons corresponding to the deadfront status indicators 26, 28, 30, and 32, as reproduced below:

FIG.22



(Application at FIG. 22.) Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

§103 Rejection of the Claims

1. Claims 1-4, 7-15 and 18-20 were rejected under 35 U.S.C. § 103(a) for obviousness over DeGroot (U.S. Patent No. 5,987,356). Of these claims, claims 7-10, 13-15, and 18-20 have been cancelled, thereby mooting this basis of rejection of those claims. With respect to the other claims 1-4 and 11-12, Applicant has amended the claims to overcome this rejection, such that no *prima facie* case of obviousness presently exists with respect to these claims because all elements are not present in this single reference being used as the basis of the obviousness rejection.

For example, Applicant cannot find in the cited portions of DeGroot, among other things, any disclosure, teaching, or even a suggestion of using handheld patient-operated user-interface device to communicate with and receive status information from an implantable cardiac rhythm management device, wherein such status information is used for:

- illuminating the normal rhythm indicative deadfront status indicator when the rhythm of the patient's heart is in normal rhythm;
- illuminating the contact caregiver indicative deadfront status indicator when some function of the implantable cardiac rhythm management device or the heart rhythm are abnormal such that it is advisable for the patient to immediately contact the patient's caregiver;
- illuminating the therapy pending indicative deadfront status indicator when a therapy has been scheduled by the implantable cardiac rhythm management device; and
- illuminating the abnormal rhythm indicative deadfront status indicator when the rhythm of the patient's heart is in an abnormal rhythm and no therapy has yet been scheduled by the implantable cardiac rhythm management device,

as similarly presently recited or incorporated in these claims. For example, although the Office Action asserts that "[i]t is noted that the patient activator is meant to be carried by the patient and therefore meets the functional use of handheld," (Office Action at 3), Applicant cannot find any disclosure, teaching, or suggestion in the cited portions of DeGroot of its patient activator being "sized and shaped to fit comfortably within an average sized adult hand" as similarly presently recited or incorporated in these claims. Regarding the status indications provided by the cited portions of DeGroot, the Office Action cites to columns 35-37 of DeGroot, which merely states:

such as tapping the implanted device or the patient holding his breath, as discussed above. In response to receipt of the patient retrigger signal, the processor will attempt to deliver the scheduled therapy at such time as all delivery and synchronization criteria are met thereafter. If no patient retrigger signal is received within the defined time interval, the processor will initiate an uplink to the patient activator to inform the patient and, after a short delay (e.g. 5-10 seconds) will attempt to deliver the scheduled therapy at such time as all delivery and synchronization criteria are met. If a pending therapy is canceled either prior to or after receipt of the patient retrigger signal, the processor will initiate an uplink to inform the patient that the therapy won't be delivered. As discussed above, the patient retrigger signal may take the form of a downlink from the patient activator or may be a sensed patient action, such as the patient holding his or her breath or tapping on the implanted device.

In a second embodiment of the invention, if the patient retrigger function is not enabled, the processor will initiate an uplink to the patient activator to inform the patient that the patient retrigger function is not enabled, and therapy will not be delivered. A third embodiment of the invention may be a hybrid of the first and second embodiments. Following the first request for therapy within a defined time period, for example 10 minutes, if the patient retrigger function is not enabled, the processor in the implanted device will initiate an uplink to the patient activator to inform the patient that the patient retrigger function is not enabled, and therapy will not be delivered. Following a second request within the defined time period, the implanted device may function as in the first embodiment, delivering therapy if possible even if the patient retrigger function is not enabled. All three embodiments may be present in the same device by means of alternately activated programming stored in the read only memory of the microprocessor, and the physician may be able to select between the three operational modes by means of an external programmer.

The methodology employed by the implanted device and patient activator in combination thus provides a mechanism for delivering patient requested therapy even if, the implanted device is unable to classify the rhythm at the time the button on the activator is pushed, so long as the criteria for delivery are met within a reasonable time thereafter. The criteria for triggering a patient activated therapy are based upon the criteria for triggering a device initiated therapy, but are less stringent, as they are a subset of the required criteria for device initiated therapy. The criteria for delivery are thus likely to be met quickly if therapy is warranted, facilitating the prompt delivery of therapy in response to a patient's request. The patient retrigger feature gives the patient increased control over the specific timing of the delivered therapy, which may allow the patient to tolerate a high energy cardioversion or defibrillation pulse and may reduce the anxiety felt by the patient in conjunction with patient requested therapies.

3. Detailed description of operation of patient activator and implanted device

FIG. 15 is a functional flow chart illustrating the operation of the patient activator *in conjunction with a request for therapy*. In response to the pressing of the activator button at 800, the power/switching/battery monitoring circuit 120 powers up the activator, and the microprocessor defines two time intervals thereafter, including interval T-1, which may be 10 seconds, and interval T-3, which may be 60 seconds. The microprocessor polls the battery monitoring circuit 120 at 802 to determine whether adequate battery voltage is present, if not, the microprocessor provides a signal to circuitry 120 at 804 to shut down the activator. If battery voltage is adequate, the microprocessor triggers the LED drivers 114 to flash both the green and amber LEDs for 250 milliseconds, which indicates that the activator is operative. At 808, the microprocessor modulates a programming data stream, which is presented to antenna driver/switching circuit 124, for transmission to the implanted device. The microprocessor then waits at 809 for a return uplink signal from the implanted device, indicating that the patient activation request has been received. On transmission of the downlink, the microprocessor also defines a time interval T-2, which for example, may be 250 milliseconds. At 810, the microprocessor determines whether it has received a valid uplink from the implanted device. If the downlink to the device was received, the corresponding uplink would start within T-2 minus the duration of the uplink (e.g. 70 ms.) following the end of transmission of the downlink. If an uplink is not received or the uplink that is received cannot be adequately decoded, the device checks at 814 to determine whether T-1 has terminated. If not, the device waits until the end of time interval T-2 at 812, and repeats the downlink transmission, until either time period T-1 has been completed, or a good uplink has been received.

If time period T-1 expires prior to receiving a good uplink from the implanted device, the microprocessor checks at 816 to see if the push button is currently being pressed, indicating that the patient still desires delivery of therapy. If not, the microprocessor signals the power/switching/monitoring circuit 120 to power down the device. If the button has not been released after expiration of time interval T-1, the microprocessor checks at 818 to determine whether time interval T-3 has expired, which is taken as an indication that communication with the implanted device simply is not possible, and the microprocessor simply shuts down the activator at 820. If the button is being pressed, and time interval T-3 has not been completed, the activator continues to send downlink patient therapy requests every 250 milliseconds, until either the button is released, or T-3 expires.

On receipt of a valid uplink at 810, the microprocessor defines two additional time periods including T-4, which may be 60 seconds since the uplink was received, and T-5, which may be 10 seconds since the uplink was received. At 822 the uplink is decoded, and the activator is notified whether or not the patient's

heart rhythm indicates that therapy is warranted at 824. If therapy is not warranted, at 828 the microprocessor triggers the speaker driver 110 to deliver an audible signal, for example, a sequence of three rising tones, and activates the LED driver circuitry 114 to flash the green indicator light on the case of the activator, indicating to the patient that therapy will not be delivered. If therapy is warranted but cannot presently be delivered at 826, the microprocessor notifies the patient at 830 by activating the speaker driver 110 to produce a different audio signal, for example, a falling two-tone sequence. In addition, the microprocessor activates the LED driver circuitry 114 to cause both the amber and the green lights to flash. In this case, the patient knows that the therapy is warranted but will not be delivered. If therapy is not going to be delivered, the processor shuts down the activator at 834. If, on the other hand, the implanted device determines that the requirements for the therapy are presently met, the microprocessor notifies the patient at 832 by a third, distinguishable audio signal, for example a steady, pulsing tone, with no LED activation. The particular audio and visual signals provided to the patient, are of course, arbitrary, and any set of similar warning signals which allows the patient to reliably distinguish between the three states, i.e., no therapy needed, therapy unavailable, and therapy pending, are believed to be workable in the context of the present invention.

FIG. 16A is a continuation of the flow chart illustrated in FIG. 15, indicating operation of the activator in the embodiments of the invention in which the implanted device detects a patient action as a retrigger signal as described above. After the activator receives an uplink indicating that the implanted device intends to deliver therapy, the microprocessor waits until either an uplink is received from the implanted device at 900, or until a predefined interval T-4, initiated on receipt of the preceding uplink, has expired. If the time interval T-4 expires without receiving an uplink from the implanted device, the microprocessor powers down the activator at 904. If an uplink is received at 906, it will occur after the implanted device has charged its high voltage output capacitors and made a determination as to whether or not the patient retrigger function should be enabled and whether the therapy has become unavailable in the interim, for example, by failure of the output capacitors to charge in the requisite time period. If therapy cannot be delivered, the patient is notified that therapy is unavailable using the same set of audible and visual signals described above at 910, and the microprocessor powers down the activator at 914. If therapy is available, but the uplink indicates that the patient retrigger function will not be enabled at 912, the patient is notified at 918, for example, by repeating the steady, pulsing tone, without LED activation, which indicated the therapy was going to be delivered at 832. If, on the other hand, the implanted device has determined that patient retriggering should be enabled, the patient is notified at 916 that patient triggered therapy is enabled, for example, by means of a pulsed, steady tone as described above, but augmented by flashing both LEDs, to indicate that the patient should thereafter trigger the delivery of the defibrillation pulse by means of the

designated action, such as tapping the housing of the device or by the patient's holding his or her breath. In the embodiment described herein, the implanted device is so configured that if it does not detect the specified patient's action, it nonetheless assumes that therapy is still desired, and delivers the therapy without patient retriggering, after sending a subsequent uplink indicating that the patient retrigger function is no longer available. For this reason, following notification at 916 that the patient retriggering function is still available, the device continues to await subsequent uplinks until expiration of T-4. Following notification that the patient retrigger function is not available at 918, the microprocessor powers down the activator at 919. The methodology illustrated in FIG. 16A allows the patient to make repeated attempts to trigger the patient-synchronized therapy, until time interval T-4 is expired or the implanted device has detected the trigger signal and delivered the requested therapy or the implanted device has determined that patient retriggered therapy should no longer be enabled.

FIG. 16B is a continuation of the flow chart of FIG. 15, illustrating an embodiment in which the activator is used to generate the patient retrigger signal. After receiving a signal indicating that therapy will be delivered, the process waits either for the receipt of an uplink at 920 or completion of time interval T-4, in the same fashion as described above in conjunction with FIG. 16A. In the event that T-4 expires without the receipt of an uplink, the patient is notified at 924 that patient retriggered therapy is unavailable, for example, by means of repetition of the steady pulsing tone previously employed at 832 to indicate therapy would be delivered. The microprocessor then powers down the activator at 926. If an uplink is received, the uplink is decoded at 928. If the uplink . . .

(DeGroot at cols. 35-37 (emphasis added).) First, although the cited portions of DeGroot apparently do provide certain information to a patient, such information is provided in conjunction with a patient's request for therapy (see DeGroot at col. 35, lines 59-60), rather than in response to a patient's status query about device or patient status, as presently similarly recited or incorporated in the claims. Second, Applicant cannot find any disclosure, teaching, or even a suggestion in the cited portions of DeGroot of, in response to a patient's status query about device or patient status, providing information instructing the patient to contact the patient's medical caregiver, as similarly presently recited or incorporated in these claims. Third, the Office Action admits that "DeGroot does not teach the use of deadfront status indicator lamps/icons . . . differentiated from each other by different non-textual pictorial graphic shapes . . ." (Office Action at 3.) Applicant respectfully submits that even if it were somehow correct to

assume that the use of different non-textual pictorial graphic shapes is notoriously well known in the art, when the invention is properly viewed as a whole, as required for the obviousness analysis, Applicant's claimed selection of particular pictorial indicators (i.e., "normal rhythm," "contact caregiver," "therapy pending," and "abnormal rhythm") are still inventive in that they have been carefully selected to most effectively provide information to a target patient population that often tends to be elderly, in ill-health, and sometimes easily confused. Therefore, Applicant respectfully submits that it is improper to deconstruct Applicant's claimed invention into various individual elements that—when analyzed individually, are asserted to be obvious—while when viewed in combination and as a whole, provide an extremely clinically useful device for a vulnerable patient population. Accordingly, because no *prima facie* case of obviousness presently exists with respect to these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

2. Claims 1-4, 7-16 and 18-20 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Musley et al. (U.S. 2004/0210256). Of these claims, claims 7-10, 13-16, and 18-20 have been cancelled, thereby mooting this basis of rejection of those claims. With respect to the other claims 1-4 and 11-12, Applicant has amended the claims to overcome this rejection, such that no *prima facie* case of obviousness presently exists with respect to these claims because all elements are not present in this single reference being used as the basis of the obviousness rejection, for reasoning somewhat similar to those discussed above with respect to the § 103 rejection using DeGroot.

In particular, the Office Action admits that "Musley does not teach the use of deadfront status indicator lamps/icons being illuminated by LEDs or different colored LEDs, having the icons/lamps differentiated from each other by different non-textual pictorial graphic shapes . . . ." (Office Action at 5.) Applicant respectfully submits that even if it were somehow correct to assume that the use of different non-textual pictorial graphic shapes is notoriously well known in the art, when the invention is properly viewed as a whole, as required for the obviousness analysis, Applicant's claimed selection of particular pictorial indicators (i.e., "normal rhythm," "contact caregiver," "therapy pending," and "abnormal rhythm") are still inventive in that they

have been carefully selected to most effectively provide information to a target patient population that often tends to be elderly, in ill-health, and sometimes easily confused. Therefore, Applicant respectfully submits that it is improper to deconstruct Applicant's claimed invention into various individual elements that—when analyzed individually, are asserted to be obvious—while when viewed in combination and as a whole, provide an extremely clinically useful device for a vulnerable patient population. Accordingly, because no *prima facie* case of obviousness presently exists with respect to these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

3. Claims 5, 6, 16 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over DeGroot (U.S. Patent No. 5,987,356) or Musley et al. (U.S. 2004/0210256) (for claims 5, 6 and 17) as applied to the claims above. Claims 16-17 have been cancelled, thereby mooting this basis of rejection of those claims. However, with respect to the other claims 5 and 6, Applicant respectfully submits that the present claim amendments have overcome this rejection, for the reasons discussed above with respect to the § 103 rejections using DeGroot and Musley.

Additionally, the Office Action admits that DeGroot or Musley fail to disclose providing a separately discernable indication of a persistent fast rhythm for 48 hours. (*See* Office Action at 6.) Instead, the Office Action appears to be taking Official Notice that such a feature would have been known in the art. Applicant respectfully disagrees. Applicant respectfully submits that the Office Action's obviousness analysis impermissibly deconstructs Applicant's claimed invention into constituent elements, rather than properly analyzing the invention as a whole, as required for the obviousness analysis. Applicant's claimed persistent fast rhythm detection criteria, in combination with the selection of particular pictorial indicators (i.e., "contact caregiver," and "abnormal rhythm") are still inventive in that they have been carefully selected to most effectively provide urgent information to a target patient population that often tends to be elderly, in ill-health, and sometimes easily confused. Therefore, Applicant respectfully submits that it is improper to deconstruct Applicant's claimed invention into various individual elements that—when analyzed individually, are asserted to be obvious—while when viewed in combination and as a whole, provide an extremely clinically useful device for a vulnerable

patient population. Accordingly, because no *prima facie* case of obviousness presently exists with respect to these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

New Claims

Applicant is presenting new claims 21-56 to more particularly and distinctly claim certain aspects of the present subject matter.

New claims 21-24 depend from independent claim 1 and are directed to displaying patient status information using a deadfront status indicator. Applicant submits that such new claims are fully supported by various portions of the specification, including the description at page 5, lines 3-22, and at page 10, line 8 to page 11, line 16.

As such, Applicant respectfully submits that no new matter is introduced. Applicant respectfully requests consideration and allowance of new claims 21-24.

Regarding new claims 25-56, in the telephonic interview of October 30, 2007, the Examiner indicated that, with the present Request for Continued Examination (RCE), Applicant would be allowed to present new claims that are shifted from the previously pending claims, but that the Examiner would consider issuing a Restriction Requirement, as the Examiner deems appropriate, with respect to such new claims. In accordance therewith, Applicant respectfully submits the following:

I. Claims 25-40. Applicant respectfully submits that new claims 25-40 are directed to recording a patient heart rhythm in response to a first or second query command. Applicant submits that such new claims are fully supported by various portions of the specification, including the description at page 12, line 22 to page 13, line 6.

II. Claims 41-48. Applicant respectfully submits that new claims 41-48 are directed to delivering therapy in response to a therapy request. Applicant submits that such new claims are fully supported by various portions of the specification, including the description at page 11, line 17 to page 12, line 21, and at page 13, lines 7-12.

III. Claims 49-50. Applicant respectfully submits that new claims 49-50 are directed to withholding therapy in response to a withhold therapy request. Applicant submits that such new claims are fully supported by various portions of the specification, including the description at page 11, line 17 to page 12, line 21, and at page 13, lines 7-12.

IV. Claims 51-56. Applicant respectfully submits that new claims 51-56 are directed to providing power to a handheld patient-operated user-interface device using a first and a second battery. Applicant submits that such new claims are fully supported by various portions of the specification, including the description at page 7, lines 14-22.

As such, Applicant respectfully submits that no new matter is introduced. Applicant respectfully requests consideration and allowance of new claims 25-56.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612) 373-6951 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date January 18, 2007 By _____
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop RCE, Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 18 day of January 2008.

KATE GAWDON _____

Name Signature